DEPARTMENT OF HEALTH AND HUMAN SERVICES

FEI: 3003466926

Food and Drug Administration
Baltimore District Office
6000 Metro Drive
Suite 101
Baltimore, MD 21215
Telephone: (410) 779-5454

WARNING LETTER

December 27, 2006

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Mr. Johnathan G. Harris, Vice President
Tienda, Inc.
3601 La Grange Parkway #200
Toano, Virginia 23168-9348

Dear Mr. Harris:

We inspected your seafood processing facility, located at 3601 La Grange Parkway #200 Toano, Virginia 23168 from August 9-24, 2006. We found that you have serious violations of the seafood Hazard Analysis and Critical Control Point (HACCP) regulation, Title 21, Code of Federal Regulations, Part 123, and the Current Good Manufacturing Practice regulation for foods, Title 21, Code of Federal Regulations, Part 110 (21 CFR 123 & 110). In accordance with 21 CFR 123.6(g), failure of a processor of fish or fishery products to have and implement a HACCP plan that complies with this section or otherwise operate in accordance with the requirements of Part 123, renders the fish or fishery products adulterated within the meaning of Section 402(a)(4) of the Federal Food, Drug, and Cosmetic Act (the Act), 21 U.S.C. § 342(a)(4). Accordingly, your vacuum packed mojama (salt cured tuna loins), and vacuum or modified atmospheric packages (flats) of white anchovies in oil and vinegar are adulterated, in that they have been prepared, packed, or held under insanitary conditions whereby they may have been rendered injurious to health. You may find the Act, the seafood HACCP regulation and the Fish and Fisheries Products Hazards & Controls Guidance through links in FDA's home page at www.fda.gov.

The deviation is as follows:

> You must conduct or have conducted for you a hazard analysis for each kind of fish and fishery product that you produce to determine whether there are food safety hazards that are reasonably likely to occur and have a HACCP plan that, at a minimum, lists the food safety hazards that are reasonably likely to occur, to comply with 21 CFR 123.6 (a) and (c) (1). A food safety hazard is defined in 21 CFR 123.3 (f) as "any biological, chemical, or physical property that may cause a food to be unsafe for human consumption." However, your firm's HACCP plan for white anchovies in oil & vinegar, and vacuum packed mojama (salted tuna) does not list the food safety hazard(s) of *Clostridium botulinum* growth and toxin formation and histamine formation.

We acknowledge receipt of your October 12, 2006 Response Letter to the FDA List of Observations left with you at the conclusion of our August 2006 inspection.

Your first comment concerned FDA Observation 1, which was your firm's lack of a HACCP plan that controls likely food safety hazards. Your letter states that Tienda has implemented temperature control logs for all refrigerators, coolers, and freezers which contain perishable products. This system of control logs will not assure the proper storage temperature of product in your refrigerators, coolers, and freezers.

Intermittent checks of the air temperature or checks of the thermometer readings are not adequate because they do not ensure that proper refrigerated temperatures were maintained between temperature checks. This includes extended periods of time when the facility is not in operation, such as overnight and during weekends. We recommend that in order to ensure maintenance of proper refrigeration temperatures, processors adopt methods that provide a continuous recording of refrigerated temperatures during refrigerated storage e.g., a continuous recording thermometer with a visual check of the instrument and the temperatures at least once per day. See the Fish and Fisheries Products Hazards & Controls Guidance: Third Edition, "the Guide". This can be found on-line at:

http://www.cfsan.fda.gov/~comm/haccp4.html .

We may take further action if you do not promptly correct these violations. For instance, we may take further action to seize your product(s) and/or enjoin your firm from operating.

You should respond in writing within fifteen (15) working days from your receipt of this letter. Your response should outline the specific things you are doing to correct these violations. You should include in your response documentation such as HACCP and verification records, or other useful information that would assist us in evaluating your corrections. If you cannot complete all corrections before you respond, you should explain the reason for your delay and state when you will correct any remaining violations.

This letter may not list all the violations at your facility. You are responsible for ensuring that your processing plant operates in compliance with the Act, the seafood HACCP regulation (21 CFR Part 123) and the Current Good Manufacturing Practice regulation (21 CFR Part 110). You also have a responsibility to use procedures to prevent further violations of the Act and all applicable regulations.

Please send your reply to the Food and Drug Administration, Attention: Randy F. Pack, Compliance Officer, 6000 Metro Drive, Suite 101, Baltimore, Maryland 21215. If you have questions regarding any issue in this letter, please contact Mr. Pack at 410-779-5417.

Sincerely,

Evelyn Bonnin
District Director